

JAN 29 2003

510 (k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: January 17, 2003

510(k) number: K030049

Applicant Information:

Rubicor Medical, Inc.
849 Veterans Blvd.
Redwood City, CA 94063

Contact Person: Ary Chernomorsky
Phone Number: (650) 556-1070
Fax Number: (650) 556-1821

Device Information:

Classification: Class II
Trade Name: Rubicor EnCapsule™ Breast Biopsy Device
Classification Name: Electrosurgical Device and accessories (21 CFR 870.4400)

Equivalent Device:

The subject device and accessory are substantially equivalent in intended use and/or method of operation to the Rubicor EnCapsule™ Breast Biopsy Device (K023601)

Intended Use:

The Rubicor EnCapsule™ Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses.

The Rubicor EnCapsule™ Breast Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with a partial or complete removal of the imaged abnormality.

The extent of histological abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g. malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Test Results:*Performance*

Results of in-vitro testing demonstrate that Rubicor EnCapsule™ Breast Biopsy Device and Stereotactic Adapter are safe and effective for their intended function.

Summary:

Based on the intended use, product, and performance information provided in this notification, the subject device and adapter have been shown to be substantially equivalent to the currently marketed and unmodified predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2003

Rubicor Medical, Inc.
c/o Robert J. Chin, Ph.D.
25 Hartford Avenue
San Carlos, California 94070

Re: K030049

Trade/Device Name: Rubicor EnCapsule™ Breast Biopsy Device
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting & coagulation device & accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 24, 2002
Received: January 6, 2003

Dear Dr. Chin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 — Dr. Robert. J. Chin

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K030049

Device Name: Rubicor EnCapsule™ Breast Biopsy Device

Indications for Use:

The Rubicor EnCapsule™ Breast Biopsy Device is intended for diagnostic sampling of breast tissue during breast biopsy procedures. It is to be used for diagnostic purposes only and is not intended for therapeutic uses.

The Rubicor EnCapsule™ Breast Biopsy Device is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with a partial or complete removal of the imaged abnormality.

The extent of histological abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g. malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the Counter Use ☐